(1) Assemblers of diagnostic x-ray systems, as defined in §1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in §1040.20(b) of this chapter.

(c) These officials may not further redelegate these authorities.

§5.604 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 537(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360nn(c)).

(b) These officials may not further redelegate these authorities.

§5.605 Dealer and distributor direction to provide data to manufacturers of electronic products.

(a) The Director and Deputy Director for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 537(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360nn(f)).

(b) These officials may not further redelegate these authorities.

§5.606 Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and Local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 541 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360rr).

(b) These officials may not further redelegate these authorities.

Subpart I—Product Designation; Redelegations of Authority

§5.700 Authority relating to determination of product primary jurisdiction.

The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, as product jurisdiction officer is authorized to make a determination under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–2) respecting the classification of a product as a drug, biological product, device, or a combination product subject to section 503(g) of the act (21 U.S.C. 353(g)), and to assign primary responsibility respecting the organizational component of the Food and Drug Administration that will regulate the product. This official may not further redelegate this authority.

§5.701 Premarket approval of a product that is or contains a biologic, a device, or a drug.

(a) For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) and the Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(2) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director, Office of Device Evaluation, CDRH.